DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 16, 2015

Medtronic, Inc.
Bruce Backlund
Principal Regulatory Affairs Specialist
7611 Northland Dr.
Minneapolis, MN 55428

Re: K150567
Trade/Device Name: Bio-Medicus Insertion Kit
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: March 2, 2015
Received: March 13, 2015

Dear Mr. Bruce Backlund,

This letter corrects our substantially equivalent letter dated April 9, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150567

Device Name
Bio-Medicus Insertion Kit

Indications for Use *(Describe)*
This kit is intended for use by trained physicians only, to assist in vessel cannulation for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed. This kit is intended for use for up to 6 hours.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared: April 7, 2015

Submitter: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
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Establishment Registration Number: 2184009

Contact Person: Bruce J. Backlund
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Common Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing.

Proprietary Name: Bio-Medicus™ Insertion Kit

Classification: Classification: Class II
Panel: Cardiovascular
Regulation: 21 CFR 870.4210
Product Code: DWF

Predicate Device: Medtronic Bio-Medicus™ Cannula Insertion Kit (K924643)

Device Description

Bio-Medicus™ Insertion Kits contains the necessary components to achieve insertion of a Bio-Medicus™ cannula and introducer. The included items are: a Seldinger needle, a guidewire, a scalpel blade, stepped dilators, and a catheter tip syringe.

Indications for Use

This kit is intended for use by trained physicians only, to assist in vessel cannulation for cardiopulmonary bypass circulation. Standard surgical or percutaneous insertion techniques can be employed. This kit is intended for use for up to 6 hours.

Comparison to Predicate Device

A comparison of the proposed product to the currently marketed Medtronic Bio-Medicus™ Cannula Insertion Kit (K924643) indicates the following similarities:

- Same intended use/indications
- Same operating principle
- Same fundamental technological characteristics
- Same overall design and performance
- Same materials
- Same packaging materials and design
- Same sterilization requirements
- Three (3) new models include additional dilator, guidewire and syringe sizes as shown in the following table:

Kit Configurations			
Model 96550 (currently marketed device K924643 S.E. December 8, 1992)	**Model 96551 (Subject of this submission)**	**Model 96552 (Subject of this submission)**	**Model 96553 (Subject of this submission)**
60-cc syringe	10-cc syringe	10-cc syringe	10-cc syringe
18 ga Seldinger style needle	18 ga Seldinger style needle	18 ga Seldinger style needle	18 ga Seldinger style needle
8/10 Fr and 12/14 Fr stepped dilator	8 Fr/10 Fr, 12 Fr/14 Fr, and 16 Fr/18 Fr stepped dilator	8 Fr/10 Fr, 12 Fr/14 Fr, and 16 Fr/18 Fr stepped dilator	8/10 Fr and 12/14 Fr stepped dilator
0.038-in (0.1 cm) x 180 cm (70.87-in) guidewire	0.038-in (0.965-mm) x 180-cm (70.87-in) guidewire	0.038-in (0.965-mm) x 100-cm (39.37-in) guidewire	0.025-in (0.535-mm) x 60-cm (23.62-in) guidewire
#11 scalpel blade	#11 scalpel blade	#11 scalpel blade	#11 scalpel blade

Summary of Performance Data

Testing has demonstrated that the Bio-Medicus™ Insertion Kits are substantially equivalent to the predicate.

The following tests were conducted to demonstrate substantial equivalence of proposed Insertion kits to the current Insertion kit (1 and 4 year data).

Component	Verification/Validation	Results
Dilator	Follows Guidewire	Pass
Dilator / Guidewire	Kink	Pass
Dilator Luer	Body Separation	Pass

Conclusion

Compared to the predicate device, the fundamental scientific technology, operating principles, design features and intended use are unchanged. As such, it has been demonstrated that the modifications made to the Bio-Medicus™ Insertion Kit described in this submission result in a substantially equivalent device.